

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

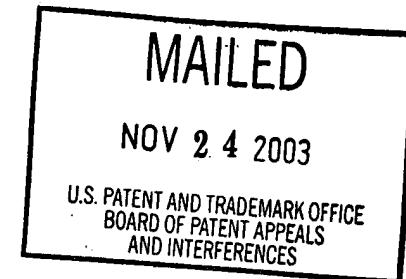
Paper No. 31

## UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KENNETH F. BUECHLER,  
JOSEPH B. NOAR, and  
LEMA TADESSE

Appeal No. 2003-1035  
Application No. 09/066,255



HEARD: October 7, 2003

WILLIAM F. SMITH, MILLS, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

#### DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 28, 30, 32, and 34. Claims 23 through 27, 29, 31, 33, and 35 are pending but have been withdrawn from consideration by the examiner. Claim 30 is representative of the subject matter on appeal and reads as follows:

30. A method for determining the presence or amount of at least one target ligand in a fluid sample, the method comprising:

a. contacting said fluid sample suspected of containing said target ligand with a ligand analogue conjugate and a ligand receptor, said ligand analogue conjugate

comprising at least one ligand analogue coupled to a signal development element comprising a water soluble hybrid phthalocyanine derivative, to form a homogeneous reaction mixture, whereby said ligand analogue conjugate competes with said target ligand for binding to said ligand receptor, wherein said water soluble hybrid phthalocyanine derivative is a tetraazapyrrole molecule, wherein (i) at least one of the four pyrrole moieties is fused to a single carbocyclic ring to form a phthalocyanine subunit, (ii) each of the other three pyrrole moieties is fused to between zero and three carbocyclic rings to form a subunit selected from the group consisting of an azaporphine subunit, a phthalocyanine subunit, a naphthalocyanine subunit and an anthranylcyanine subunit, and (iii) at least two of the four pyrrole moieties comprises a different number of carbocyclic rings fused thereto;

- b. generating a detectable signal from ligand analogue conjugate that is not bound to said ligand receptor in said reaction mixture; and
- c. relating the detectable signal to the presence or amount of said target ligand in said fluid sample.

The references relied upon by the examiner are:

Freytag	4,434,236	Feb. 28, 1984
Stanton et al. (Stanton)	4,803,170	Feb. 7, 1989
Renzoni et al. (Renzoni)	5,135,717	Aug. 4, 1992

Margaron et al. (Margaron), "Photodynamic properties of naphthosulfobenzo-porphyrazines, novel asymmetric, amphiphilic phthalocyanine derivatives," J. Photochem. Photobiol. B., Biol., Vol. 14, pp. 187-199 (1992)

Claims 28, 30, 32, and 34 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 30 and 34 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Margaron, Renzoni, and Freytag. Claims 28 and 32 also stand rejected under 35 U.S.C. § 103 with the examiner relying upon Margaron, Renzoni, Freytag, and Stanton as evidence of obviousness. We reverse all rejections.

Discussion

1. Claim definiteness.

The sole reason given for the rejection is:

The claims contain the term 'ligand analogue', which is deemed to be indefinite. It is not clear what are the similarities and differences between the ligand and the ligand analogue; that is, how 'analogous' must these two compounds be? Thus, it is impossible to determine the metes and bounds of the invention and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Examiner's Answer, page 4.

It has long been held that definiteness of claim language must be "analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971)(footnote omitted). Here, it is apparent that the examiner's reasoning in support of the rejection does not comport with this legal standard. Merely asking the question "how 'analogous' must these two compounds be?" indicates that the examiner considered the issue in an impermissible vacuum, not in light of the prior art and the written description of this application. What is needed is a fact-based statement of a rejection using the correct legal standard. Since we do not have such a statement for review in this appeal, we reverse the rejection under 35 U.S.C. § 112, second paragraph.

2. Obviousness.

The key to the claimed invention is the use of a water-soluble hybrid phthalocyanine derivative. In relevant part, that compound is to have "at least two of the four pyrrole moieties comprise a different number of carbocyclic rings to fuse thereto," i.e., the compound is asymmetrical. The examiner refers the reader of the Examiner's Answer to Paper No. 12 for a statement of the prior art rejections. In reviewing those rejections, we find the logic and fact-finding of the examiner to be at best confusing.

The claims on appeal are directed to a method for determining the presence or amount of at least one target ligand in a fluid sample. As a matter of logic, one would expect the examiner's so called primary reference to describe such a method to some degree. However, the examiner has built the rejection based upon Margaron which describes water soluble hybrid phthalocyanine derivatives used in photodynamic therapy of cancer. The examiner states that Margaron "lacks the teaching of using these compounds in a conjugate." Paper No. 12, page 5. The examiner builds upon Margaron by relying upon Renzoni as teaching "water-soluble phthalocyanine derivatives (see column 3, lines 29-55) that read directly on those of the instant claims." Id. The examiner concludes that Renzoni "lacks a specific teaching of a competitive assay as recited in the claims." Id.

Finally, the examiner relies upon Freytag for its description of "an assay that is the same as the one claimed, except for the fact that Freytag uses different labels for the antibodies than the ones of the instant claims . . ." Id. The examiner concludes:

However, one of ordinary skill in the art would know that such labeled antibodies could be used in a competitive assay, because such assays were very well known in the art at the time of filing. For example, Freytag teaches an assay that is the same as the one claimed, except for the fact that Freytag uses different labels for the antibodies than the ones of the instant claim (see Abstract, Examples and claims 1-7 of the reference). However, Freytag does discuss that fluorophores can be used for labeling the antibodies (column 3, lines 43-48).

Paper No. 12, paragraph bridging pages 5-6.

Apart from the backward logic of the examiner's assemblage of the references, the fact-finding performed by the examiner in stating the rejection is inconsistent. As set forth above, the examiner found the water soluble phthalocyanine derivatives of Renzoni "read directly on those of the instant claims." Examiner's Answer, page 5. However, the examiner stated in responding to appellants' arguments on appeal "[t]he examiner recognizes that the phthalocyanine derivatives of Renzoni . . . are not 'hybrid phthalocyanine derivatives' as instantly defined. . . ." Id., page 12. The examiner cannot have it both ways. Either the phthalocyanine derivatives of Renzoni read upon those required by the claims on appeal or they do not. In reviewing the section of Renzoni cited in support of the examiner's finding that the water soluble phthalocyanine compounds of that reference read upon those required by the claims on appeal, we do not find the asymmetric water soluble hybrid phthalocyanine derivatives of the claims on appeal are described. Accordingly, the examiner's rejection is deficient for at least that reason.

Another aspect of the examiner's fact-finding which is confusing concerns the requirement of the claims on appeal that a ligand analogue conjugate be used. The

claimed ligand analogue conjugate comprises at least one ligand analogue coupled to a signal development element comprising the defined asymmetric water soluble hybrid phthalocyanine derivative. The examiner states that the phthalocyanines of Renzoni are "conjugated to biologically active agents such as antibodies . . . , peptides or nucleotides . . ." In stating her ultimate conclusion of obviousness, the examiner again relies upon Renzoni as teaching a "conjugate." Examiner's Answer, page 5. However, the claims on appeal do not merely require that the water soluble hybrid phthalocyanine derivative be conjugated in a general sense or to an unknown moiety. Rather, the claims on appeal require that the water soluble hybrid phthalocyanine derivative be conjugated to at least one ligand analogue. The examiner has not adequately explained how Renzoni or Freytag describe a conjugate of a ligand analogue with a fluorophore as required by the claims on appeal.

Be that as it may, we agree with the examiner that Margaron does describe asymmetric water soluble hybrid phthalocyanine derivatives as required by the claims on appeal. However, Margaron only describes the use of those compounds in photodynamic therapy of cancer where they are stated to show improved cell penetration and photodynamic activity. Id., page 188. We recognize that the examiner relies upon two statements in Margaron for the "motivation" to combine the references. Margaron discusses that "light above 680 nm allows for deeper penetration into biological tissues as well as the availability of less expensive and more reliable light sources at these higher wave lengths." Id., pages 187-188 (reference citation omitted). However, those advantages are for photodynamic therapy of cancer, not

immunoassays. The examiner also cites to "columns 1-2" of Renzoni in the paragraph bridging pages 10-11 of the Examiner's Answer. Without a more specific citation to Renzoni by the examiner, it is impossible for us to determine the examiner's precise position. Our review of columns 1 and 2 of Renzoni does not reveal any information that would support the examiner's proposed combination of the references.

In regard to the rejection of claims 28 and 32, we do not find the examiner's reliance upon Stanton to rectify the deficiencies set forth above in the examiner's reliance upon Margaron, Renzoni and Freytag.

The obviousness rejections are reversed.

The decision of the examiner is reversed.

REVERSED

William F. Smith )  
William F. Smith )  
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 )  
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